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C. O'Brien, B.S. Cadarette, T.L. Endrusick, L.A. Blanchard, X. Xu, L.G. Berglund, M.N. Sawka, R.W. Hoyt

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14. ABSTRACT

As part of the U.S. Army materiel development and acquisition process, clothing and individual equipment (CIE) must undergo a Health Hazard Assessment (HHA) conducted by the U.S. Army Center for Health Promotion and Preventive Medicine. Scientists at the U.S. Army Research Institute of Environmental Medicine (USARIEM) are world experts in thermal physiology, biophysics, and biomedical modeling and are uniquely capable of providing technical measurements and subject matter expertise for thermal stress associated with CIE. A comprehensive evaluation of thermal stress involves: 1) biophysical measurements of the thermal insulation and moisture permeability of textiles using a guarded hot plate, and of garments using thermal manikins; 2) biomedical modeling to predict physiological (body temperatures, sweating rate and heart rate) strain expected of Soldiers wearing the CIE under conditions of environmental (temperature, humidity, air motion, radiant lead) and metabolic (work, rest) stressors; and 3) human volunteer testing of CIE worn by persons exposed to a variety of controlled (laboratory or field) environmental and metabolic stressors.

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USARIEM TECHNICAL NOTE TN08-01

GENERAL PROCEDURE FOR PROTECTIVE CLOTHING AND EQUIPMENT EVALUATIONS RELATIVE TO HEAT AND COLD STRESS

Catherine O'Brien
Bruce S. Cadarette
Thomas L. Endrusick
Laurie A. Blanchard
Xiaoxiang Xu
Larry G. Berglund
Michael N. Sawka
Reed W. Hoyt

Thermal and Mountain Medicine Division
and
Biophysics and Biomedical Modeling Division

September 08

U.S. Army Research Institute of Environmental Medicine
Natick, MA 01760-5007

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Human subjects participated in these studies after giving their free and informed voluntary consent. Investigators adhered to AR 70-25 and the USAMRMC Regulation 70-25 on the use of volunteers in research.

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LIST OF ABBREVIATIONS

CBRNE – Chemical, Biological, Radiological, Nuclear, and Explosive

CIE – Clothing and Individual Equipment

ECWCS – Extended Cold-Weather Clothing System

GHP – Guarded Hot Plate

HA – Heat Acclimation

HHA – Health Hazard Assessment

HSDA – Heat Strain Decision Aid

JPACE – Joint Protective Aircrew Ensemble

JWARN – Joint Warning and Reporting Network

PSDA – Probability of Survival Decision Aid

SCTM – Six Cylinder Thermoregulatory Model

SME – Subject Matter Expert

TM – Thermal Manikin

USACHPPM – U.S. Army Center for Health Promotion and Preventive Medicine

USAMRMC – U.S. Army Medical Research and Materiel Command

USARIEM – U.S. Army Research Institute of Environmental Medicine

USCG – U.S. Coast Guard

EXECUTIVE SUMMARY

As part of the U.S. Army materiel development and acquisition process, clothing and individual equipment (CIE) must undergo a Health Hazard Assessment (HHA), which is conducted by the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM). Candidate CIE frequently requires an HHA for thermal stress. Scientists at the U.S. Army Research Institute of Environmental Medicine (USARIEM) are world experts in thermal physiology, biophysics, and biomedical modeling and are uniquely capable of providing technical measurements and subject matter expertise (SME) for thermal stress HHA. HHAs are performed for acoustic energy, biological and chemical substances, oxygen deficiency, radiation energy, shock, vibration, trauma, and temperature extremes (thermal stress). A comprehensive evaluation of thermal stress associated with clothing / equipment involves the following: 1) biophysical measurements of the thermal insulation and moisture permeability of the textiles using a guarded hot plate, and of the garments using thermal manikins; 2) biomedical modeling to predict physiological (body temperatures, sweating rate and heart rate) strain expected of Soldiers wearing a particular CIE configuration under conditions of environmental (temperature, humidity, air motion, radiant lead) and metabolic (work, rest) stressors; and 3) human volunteer testing of CIE worn by persons exposed to a variety of controlled (laboratory or field) environmental and metabolic stressors. Human volunteers can also provide feedback on user acceptability. This technical note describes the progression of procedures to support the HHA of thermal stress for candidate CIE. Each of the procedures is described in detail to indicate how the testing is conducted and what information can be obtained.

This technical note is an update of USARIEM TN95-5, General Procedure for Clothing Evaluations Relative to Heat Stress, 1995 (25).

INTRODUCTION

As part of the development and acquisition process, Army materiel must undergo a Health Hazard Assessment (HHA; IAW AR 40-10 (42)), which is conducted by the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM). HHAs are performed for acoustic energy, biological and chemical substances, oxygen deficiency, radiation energy, shock, vibration, trauma, and temperature extremes (thermal stress). One of the most serious health hazards related to clothing systems, particularly protective clothing and equipment (CIE), is thermal stress. CIE typically require an HHA for thermal stress. Studies supporting an HHA generally compare the thermal stress imposed by a prototype item to an existing item or standard.

CIE are often designed to protect against natural or man-made hazards, and include firefighting uniforms; chemical, biological, radiological, nuclear, and explosive (CBRNE) protective clothing (29); and extreme cold weather clothing systems (ECWCS). Heat stress is elevated when wearing CIE due to the weight and bulk of the CIE, which increase metabolic demands (32), as well as their insulation and low water vapor permeability characteristics, which limit the ability to dissipate heat (28). The

combination of clothing characteristics, environmental conditions and metabolic rate can result in either heat or cold stress. For example, heat stress can occur during cold exposure if CBRNE protective clothing is worn in combination with ECWCS while working at a high metabolic rate; however, during rest periods, excessive heat loss can occur (10, 52). In cold weather, extremity temperatures, rather than body core-skin temperatures, may be the critical factor in the HHA (52).

The systematic evaluation of clothing using biophysical evaluations to determine insulation and permeability of textiles and ensembles; biomedical modeling to predict thermal stress; and human testing to measure physiological responses under specific conditions provides much more information than any single approach. For example, Young et al. (52) used modeling to extend the limited existing physiological data on CBRNE clothing in cold environments to predict core and skin temperatures and evaporative heat loss during work-rest cycles at temperatures from -10ºC to -30ºC. The modeling data highlighted the conditions where core temperatures indicated heat strain and where skin temperatures indicated excessive cooling.

Biophysical evaluations of textile and clothing ensembles are often a cost-effective and rapid way to determine insulation and permeability differences that may negate the need for subsequent human testing. For example, recent manikin testing demonstrated no differences in insulation and permeability between the current Army Combat Uniform made from 50% cotton / 50% nylon textile and a newly developed Army Combat Uniform made from 100% flame resistant rayon textile.

Biomedical modeling approaches can be both empirical; i.e., based on data from physiological testing, or rational; i.e., derived from accepted physiological principles. When empirical models are developed from a large number of studies under a wide range of conditions, the model can successfully extend the data to predict physiological responses under new conditions (e.g.; different environmental temperatures, work rate and duration, or type of clothing). Rational models may be better able to account for individual variability in anthropometrics, physical fitness, and responses to heat strain.

Human testing may be required to provide accurate data on thermal strain under specific physiological and environmental conditions. Human testing is also critical for evaluation of clothing systems, such as the Joint Protective Aircrew Ensemble (JPACE) (7) or microclimate cooling systems for use with chemical protective clothing (6).

The U.S. Army Research Institute of Environmental Medicine (USARIEM) has world experts in thermal physiology, biophysics, and biomedical modeling and, therefore, is in a unique position to provide technical measurements and subject matter experts (SME) to support HHA for thermal (heat and cold) stress. This Technical Note describes the progression of procedures to support the HHA of thermal stress for candidate CIE. Each of the procedures is described in detail to indicate how the testing is conducted and what information can be obtained. HHA evaluations help to protect Soldier health and sustain Soldier performance. USARIEM has been vital in supporting

USACHPPM thermal stress HHA for more than 40 years by providing technical and SME leadership.

TERMINOLOGY

Throughout this technical note, thermal "stress" refers to the environmental conditions that cause an individual to gain or lose heat; whereas thermal "strain" refers to the physiological responses of the individual. Environmental conditions (temperature, humidity, radiant load, wind speed), physiological factors (anthropometrics, fitness, hydration, nutrition, acclimatization, rest / fatigue, health, medication), and mission factors (uniform, load carriage, terrain, work rate) all interact to produce thermal stress (40, 41). Physiological signs of heat strain include increased sweat rate, increased heart rate, and elevated body (core and skin) temperatures. Physiological signs of cold strain include decreased skin temperature (particularly extremity temperatures), elevated metabolic rate (shivering), and decreased body core temperature.

BIOPHYSICAL EVALUATIONS

The initial testing of clothing systems begins with a biophysical evaluation of textile materials, followed by evaluation of the actual CIE on the thermal manikin (15, 17). The currently fielded textile materials and clothing systems are typically used as controls for comparative evaluations. Thermal characteristics (thermal insulation (clo) and water vapor permeability (i_m)) of textile samples are measured using a guarded hot plate (14), which is operated in accordance with International Organization for Standardization (ISO) Standard 11092 (21). The thermal characteristics of CIE are determined using a thermal manikin. These data are used to develop heat exchange coefficients (i_m/clo; evaporative resistance) that allow comparison of the evaporative cooling or heat loss capacity of each ensemble. These clothing coefficients are derived from thermal manikin experiments conducted at a range of ambient air velocities and are used in USARIEM models. These models are especially important for predicting physiological strain (e.g., body temperatures, sweating, shivering, heart rate) under environmental conditions that may be too risky for human volunteers, or for predicting physiological strain for a large number of scenarios (such as multiple environmental conditions and / or multiple CIE) where cost of human testing would be prohibitive.

HEAT TRANSFER GLOSSARY

The following terms are used in the biophysical evaluation of the thermal characteristics of fabrics and clothing:

clo Unit of thermal resistance to heat flow through textile material (Insulation). 1 clo = 6.46 W/m^2 of surface area per degree Celsius difference between skin and ambient temperatures.

i_m Water vapor permeability index for evaporative heat loss (Permeability). A dimensionless number from 0-1, 0 being impermeable.

i_m/clo Ratio of permeability to insulation (Evaporative Resistance). The higher the i_m/clo ratio, the greater the potential for evaporative cooling and, therefore, heat loss.

GUARDED HOT PLATE

Guarded hot plate (GHP) testing measures the dry and wet (evaporative) heat transfer through single or multiple layered textile materials to determine insulation and permeability values (14, 21). A small (~35 cm^2) sample of material is placed on a temperature-controlled flat plate in a controlled environmental chamber. The procedure is designed to simulate the heat transfer that occurs in the microclimate created between the human skin surface, the various textile layers (i.e., clothing), and the surrounding ambient atmosphere. An advantage of GHP testing is that it can quickly evaluate and rank a large number of similar materials. However, the thermal resistance and vapor permeability values measured for a flat, two-dimensional sample may not be the same when the material is used to construct an actual garment. Although ranking relative to other materials will probably not change, the difference in insulation and permeability measured on the GHP may be larger than those measured on a full-sized thermal manikin. This can occur simply by combining materials and adding seams and fasteners in the construction of a garment. Therefore, a material typically only proceeds for evaluation in garment form on the thermal manikin if GHP tests show that it is significantly better than the standard or control material (>0.1 clo or >0.03 i_m/clo difference), and/or if the material passes a selection based on ranking.

THERMAL MANIKIN

Thermal manikin (TM) testing measures dry and wet heat transfer of CIE worn by a heated, sweating manikin in a controlled environmental chamber. The advantage of TM testing is that heat transfer characteristics are evaluated on a complete ensemble as it is designed to be worn, accounting not only for the properties of the specific textiles, but also for garment design and drape on the manikin form, as well as the added influence of individual combat equipment, such as body armor. Articulated manikins simulating human locomotion also measure the effect of air movement within the microclimate of the clothing on heat and water vapor transfer.

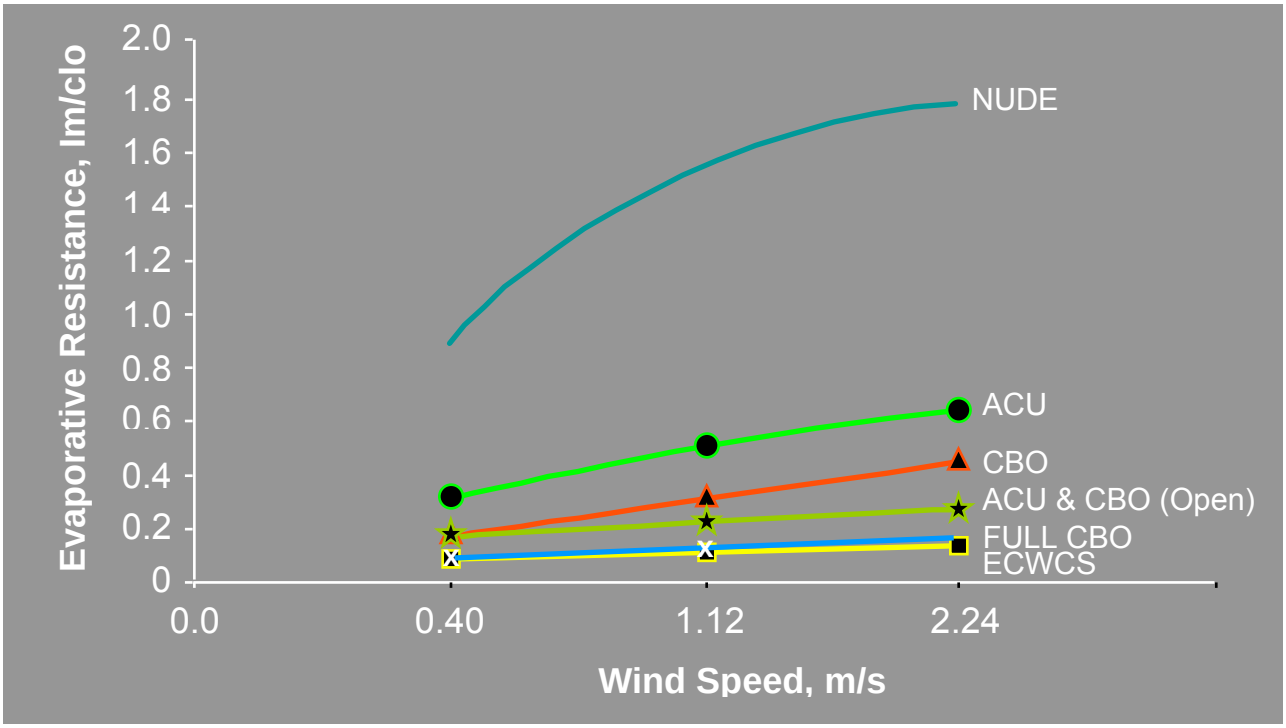
Thermal insulation and evaporative cooling potential (vapor permeable index) of clothing ensembles are evaluated using accepted standard operating procedures on a life-sized TM (5, 17, 44-46). The TM, equipped with computer-controlled capabilities, is outfitted with a tight, form-fitting suit that can simulate a sweating human with a 100% wetted surface area by completely saturating the suit with water. A standard reference garment (e.g., Army Combat Uniform, or other standard-issue clothing) should be used

as a reference control to compare the thermal properties of each prototype ensemble being evaluated (5).

The standard procedures used in operating the TM include regulation of the manikin surface at a constant temperature, and controlling ambient temperature, relative humidity and air velocity in the climatic chamber housing the manikin. The most widely accepted test procedures for the operation of a TM are published by the American Society for Testing and Materials (ASTM). ASTM F 1291-05, "Standard Test Method for Measuring the Thermal Insulation of Clothing Using a Heated Manikin" (2), describes measurement of the clo value of a complete clothing ensemble. It requires a TM surface temperature of 35ºC and a climatic chamber controlled at 23ºC, 50% relative humidity with a 0.4 m/sec air velocity. ASTM F 2370-05, "Standard Test Method for Measuring the Evaporative Resistance of Clothing Using a Sweating Manikin" (1) measures the i_m of a complete clothing ensemble. It requires a TM surface temperature of 35ºC and a climatic chamber controlled at 35ºC, 40% relative humidity, with a 0.4 m/sec air velocity. In addition to the tests conducted at 0.4 m/sec, USARIEM also conducts tests at two higher wind speeds to allow accurate determination of the effect of increased air movement on the thermal transfer properties of the clothing (19). This effect can be seen in Figure 1 for several clothing ensembles. These data can be entered into computer models to predict human thermoregulatory responses under a variety of environmental and work intensity conditions.

If TM tests indicate there is enough difference (≥ 0.1 i_m/clo) between a control and a prototype ensemble to be within the resolution of human testing, it is usually recommended that the prototype ensemble be evaluated during a controlled human wear test. When TM differences are small (<0.1 i_m/clo) and unlikely to produce significant differences in physiological strain during human testing, modeling alone may be used for further evaluation. However, human testing may be requested to document human physiological strain, even when comparisons are not likely to reveal significant differences. For HHA, decisions regarding testing are made in concert with CHPPM.

Figure 1. The effect of wind speed on Evaporative Resistance is shown for a nude manikin, and when wearing the Army Combat Uniform (ACU), Chemical Biological Overgarment (CBO), and Extended Cold Weather Clothing System (ECWCS).



BIOMEDICAL MODELING

Biomedical modeling presents a means of estimating physiological strain over a variety of environmental and metabolic conditions (18). Models may be empirical; i.e., mathematical functions fit to actual data obtained from human studies, or rational; i.e., based on accepted physical laws and physiological principles. Data from biophysical evaluations of clothing ensembles is important to the models for accurate determination of heat and vapor transfer. Models are most useful across the range of conditions for which they were developed. Validation of models is an ongoing process, and improvements are made as data from thermal manikin and human studies become available.

EMPIRICAL MODELS

The USARIEM Heat Strain Decision Aid (HSDA) is an example of an empirically developed operational model based on the results of thousands of experiments. The volunteers for these experiments were primarily male Soldiers between the ages of 18-25 who were fit for regular duty. They were well rested between trials and performed military duties such as road marching (treadmill walking), tank driving, and marksmanship in various climates while their physiological responses were recorded. Results obtained from the HSDA, therefore, reflect the physiological responses of this

particular population. The HSDA is well established and is used by groups such as the Ranger Training Brigade and the Joint Warning and Reporting Network (JWARN). Inputs to this model, shown on Table 1, include environmental conditions, mission-related requirements (e.g., work intensity or work / rest cycles), and anthropometric characteristics known to affect thermoregulatory responses. Clothing parameters derived from thermal manikin evaluations are also used as inputs in this model and provide critical information about heat transfer. Additional inputs, such as heat acclimatization and hydration status, are also important because of the impact they have on thermoregulatory responses (34). While the output parameters from the HSDA shown on Table 2 pertain to mission performance, the limits are based on the prediction of core temperature. For HHA, the actual predicted core temperature and estimated number of heat casualties under different conditions may be the outputs of interest.

Table 1. Input variables for the USARIEM Heat Stress Decision Aid (HSDA).

Input	**Range**
dry bulb temperature (T_{db}) [°C]	$10 \leq T_{db} \leq 50$
relative humidity (RH) [%]	$0 \leq RH \leq 100$
wind speed (ws) [m/s]	$0 \leq ws \leq 10$
mean radiant temperature (T_{mr})[°C]	$T_{db} \leq T_{mr} \leq (T_{db} + 40)$
altitude (alt_m) [m above sea level]	$0 \leq alt\_m \leq 4000$
work rate (W) [W]	$100 \leq W \leq 800$ (resting – very heavy work)
acclimatization (accl) [# of days]	$0 \leq accl \leq 12$
dehydration (dehyd) [%]	$0 \leq dehyd \leq 6$
uniform	**limited to i_m and clo data from thermal manikin tests**
height (ht) [cm]	$120 \leq ht \leq 215$
weight (wt) [kg]	$40 \leq wt \leq 145$

Table 2. Output parameters from the USARIEM Heat Stress Decision Aid (HSDA).

Output	**Range**
maximum work time, up to 5 hours (mxwrk) [min]	$0 \leq mxwrk \leq 300$
water requirements for one-time continous work bout (wtr_mx) [qt/h]	$0 \leq wtr\_mx \leq 1.5$
recommended work rest cycles, for up to 5 h intermittent work (wrc) [min/h]	$0 \leq wtrmx \leq 60$ *
water requirements for work rest cycles (wtr_wrc) [qt/h]	$0 \leq wtr\_wrc \leq 1.5$
estimated heat casualties if guidance is not followed (heatcas) [%]	$0 \leq heatcas \leq 100$

RATIONAL MODELS

Rational models are constructed using established physiological principles. Because they incorporate known physiological responses, they may be suitable for use in a wider range of conditions, and more adaptable to account for individual variability in anthropometrics, physical fitness, and responses to heat strain.

The Six Cylinder Thermal Model (SCTM) and SCENARIO are examples of rational models developed at USARIEM. In the SCTM, the six cylinders represented are torso, each limb, and head. This allows the modeling to account for redistribution of blood flow to or from the extremities. SCENARIO (16, 23) uses a six compartment model to simulate sweating and circulatory changes under different environmental conditions and metabolic activity levels in order to predict body core temperature. These compartments include core, muscle, fat, vascular skin, avascular skin and clothing. Heat production occurs due to basal metabolic rate, exercise, and, under cold conditions, shivering. Heat transfer throughout the body occurs by conduction across tissues and blood convection. Heat loss by evaporation, radiation, conduction and convection depend on the environmental conditions.

The Probability of Survival Decision Aid (PSDA) (47) model was developed for the U.S. Coast Guard (USCG) to estimate mortality due to heat or cold strain during man-overboard incidents. It predicts survival time for hypothermia and dehydration during prolonged exposure at sea in both air and water, such as a victim in the water or floating in an emergency craft. PSDA consists of (a) the SCTM, (b) an empirical water loss equation developed from physiological data, and (c) a Graphic User Interface (GUI) to manage inputs, run the models, and display output (47). Clothing inputs for the PSDA include heat transfer characteristics of survival suits designed for protection in case of emergency immersion. While the output of interest for the USCG is survival time, the model predicts core temperature which would be most relevant for HHA.

Although historically most models at USARIEM have focused on whole-body responses, recent efforts have been devoted to extremity models, such as predicting manual dexterity performance in the cold (50), or the effect of extremity cooling on lowering brain temperature (49). Such models could also be used to predict when dexterity (influencing performance) or peripheral cold injury (e.g., frostbite) would occur, and would be useful for evaluation of handwear or footwear (48) for thermal protection.

HUMAN PHYSIOLOGICAL TESTING

Human testing can be conducted independently or in conjunction with biophysical evaluations and biomedical modeling, although ideally all three evaluations will be performed so that a comprehensive understanding of the CIE's influence on human physiological strain under a variety of conditions can be obtained. Human testing is the only way to obtain accurate data on how CIE impacts the physiological strain of a given military scenario. Textile properties may change when garments are worn, especially with movement, changing body temperatures, or sweat absorption. Human testing is also important for continued refinement of models that will be used to extend evaluations to other conditions. Finally, user acceptability can only be obtained by human testing, ideally under conditions that closely simulate operational scenarios.

HEAT STRESS

Humans can maintain normal body (core and skin) temperatures within a wide range of environmental conditions, assuming heat transfer is not impaired. Heat dissipation occurs through dry heat loss (radiation and convection) and evaporative heat loss (sweating). Peripheral vasodilation increases blood flow to the skin, enhancing convective heat transfer from the core, and increasing sweating (43). These responses are accompanied by cardiovascular changes including increased heart rate and reduced blood flow to the gastrointestinal tract and inactive tissues (43). Increased blood flow to the skin for convective heat transfer and increased sweating (under compensable heat stress conditions) indicate heat strain in an individual (37). When the heat load exceeds the body's ability to dissipate heat, heat strain increases and heat illness / injury can occur. Pathological states of heat strain include heat exhaustion, heat injury and heat stroke (40). Cognitive and physical performance decrements can occur at hyperthermic and / or dehydration levels lower than those causing heat injury (35, 36). Army guidance for heat stress control and heat casualty management is published in Technical Bulletin Medical 507 (40).

CIE can exacerbate heat strain by limiting heat transfer in individuals working in hot environments. This is particularly true of CIE with limited permeability that blunt evaporative heat loss (29).

COLD STRESS

Humans depend on both behavioral and physiological thermoregulation for protection during cold stress. Behavioral thermoregulation includes clothing and shelter for insulation against low temperatures and protection from wind, and exercise for increasing metabolic heat production. Physiological responses to cold stress include vasoconstriction and shivering. Peripheral vasoconstriction reduces convective heat transfer between the body's core and shell (skin, subcutaneous fat and skeletal muscle). Vasoconstriction begins as skin temperature falls below about 35°C, and becomes maximal when skin temperature is about 31°C (38). Extremity temperatures (fingers, toes) fall most quickly, as their large surface area to volume ratio facilitates heat loss while vasoconstriction minimizes heat supply from blood flow. As cooling continues, the temperature of underlying tissues also falls, resulting in decreased function of nerves, muscles and joint mobility, all of which degrade physical performance (20). In the extremities, cold-induced vasodilation (CIVD), a transient increase in blood flow, may occur, offering some protection against cold injury (11). Shivering increases in response to lowered skin temperature and increased heat loss. Shivering increases metabolic heat production through involuntary, repeated, rhythmic muscle contractions, and may reach two to three times resting metabolism during sedentary exposure to cold air (33). Although a higher rate of heat production can be obtained with exercise, shivering can be sustained longer. Army guidance for prevention and management of cold-weather injuries is published in Technical Bulletin Medical 508 (41).

Cold strain can occur if clothing has insufficient insulation or if vapor transfer is limited, resulting in wet skin or damp clothing. During exercise in nuclear, biological,

chemical (NBC) protective clothing, individuals may actually experience heat strain, but sweat accumulation in clothing may decrease insulation, thereby increasing susceptibility to hypothermia upon subsequent rest (52). Excessive cold stress can result in a variety of cold injuries (41). Non-freezing cold injuries may occur if the skin stays cold and wet for extended periods of time. Freezing cold injuries (frostbite) occurs when skin temperature falls below freezing. Hypothermia occurs when heat loss exceeds heat production and body core temperature falls below 35ºC.

LABORATORY STUDIES

Human volunteer testing in the laboratory allows actual use of CIE on individuals under a range of environmental conditions, during rest and exercise, and performing specific tasks. The primary benefit of laboratory testing is the ability to control all variables so that any differences observed between experimental conditions can be attributed to the CIE. Thermal measurements are made, and user acceptability can be assessed. Laboratory studies conducted in environmental chambers provide the same conditions on separate days, ensuring appropriate comparison of experimental clothing systems to a control. Typically the same subject performs trials with each clothing configuration for a repeated measures design. Tests are conducted at the same time of day to account for body temperature changes due to circadian rhythm.

Use of Humans in Research

For any clothing evaluations using human test volunteers, whether conducted in a laboratory or field setting, investigators must adhere to guidelines established for research on humans. At USARIEM these include AR 70-25, Use of Volunteers as Subjects of Research; USARIEM 70-25, Use of Volunteers in Research; USARIEM M 70-68, Quality Assurance for Research; and the USARIEM Human Research Protection Program Policies. Investigators must follow the guidelines and limitations of USARIEM M 70-25-1, Human Research Methods for Studies in the Areas of Thermal, Hypoxic, and Operational Stress, Exercise, Nutrition, and Military Performance, which provides information and explanations about conditions, standards and safeguards that must be used during human testing. Any evaluation that uses human volunteers must be detailed in a protocol, which undergoes both scientific and human use review by institutional review boards. This process may take several weeks to a few months, depending on the level of risks to volunteers. The conditions of the study may be limited by scientific or ethical reasons associated with exposure of human volunteers to stressful environments.

Test Subjects

Volunteers selected as test subjects should be healthy, fit for duty, 18-35 years old, and medically cleared to participate in the study. Volunteers will be excluded if they have any medical condition that indicates the conditions of the study (e.g., heat exposure, exercise) would pose greater than normal risk. Volunteers may also need to meet test-specific criteria, such as limits on use of alcohol, nicotine, dietary

supplements, or medications. Female volunteers must not be pregnant and not plan to become pregnant for the duration of the study. Volunteers must be provided with a detailed informed consent document and allowed adequate time to ask questions and consider the information before choosing to volunteer for the research by signing the document. Volunteers must be informed that they can withdraw from testing at any time without penalty or prejudice, and that the investigator can remove them from the study at any time to safeguard their health if it is determined they cannot safely complete the study requirements.

Preliminary Measurements

Anthropometric data are recorded for all volunteers, including age, height, weight, body composition (typically estimated from skinfold thickness (12) or by taping as outlined in AR 600-9 (39)), and fitness level (based on 2 mile run time or measured during an aerobic exercise test). These data are important to characterize the population and provide inputs for future modeling.

Exercise-Heat Acclimation

Before beginning any trials for CIE evaluation during heat stress, volunteers should complete 5-10 days of exercise-heat exposures, referred to as Heat Acclimation (HA). Physiological responses to heat stress, including heart rate, core temperature, and sweating rate are affected by the individual's HA status (43). By completing HA before experimental trials, investigators can ensure that the physiological responses are stable day-to-day, and that data will not be confounded by thermoregulatory status during trials. For example, adaptations to HA include increased skin blood flow and onset of sweating at a lower core temperature, which results in a lower core temperature and lower heart rate for a given heat stress. Since core and skin temperatures are primary criteria measures, HA is critical to minimizing variability among trials.

Exercise for HA is typically performed for 100-110 min at a moderate intensity (325-450 W) using the same mode of exercise (e.g., treadmill walking, cycle ergometry, etc.) to be used during the CIE tests. The exercise may be either continuous for 100 min or performed as two 50-min exercise bouts separated by 10 min rest. The environmental condition is chosen to provide sufficient stress to elicit adaptations in thermoregulatory response mechanisms. Hot-dry (45°C or 113°F, 20% RH) conditions allow evaporation of sweat and are better tolerated by volunteers than more humid conditions. Clothing worn for HA sessions is typically physical training uniform (T-shirt, shorts, socks and sneakers) so that volunteers are comfortable, sweat evaporation is not impeded, and footwear does not cause blisters.

Hydration should be maintained during HA sessions to promote efficient adaptation to heat stress, with minimal additional heat strain due to hypohydration (34). This is accomplished by measuring nude body weight before and after each HA session

to ensure that body weight is restored to within 1% of the baseline weight. Body weight measurements should be made at the same time of day throughout the HA process.

Cold Acclimation

Physiological adaptations to cold stress are much smaller and occur more slowly than adaptations to heat; therefore, cold acclimation is typically not required before conducting experimental trials in the cold (51). Furthermore, during cold stress, CIE is evaluated for its ability to limit or prevent cooling; therefore, adaptations are unlikely to be elicited by the experimental trials themselves. Hydration status is also not critical for studies conducted in cold environments, as moderate dehydration does not significantly alter thermoregulatory responses (31) or physical performance (9, 22) during cold exposure.

Familiarization

Volunteers will be fitted to and familiarized with all CIE before experimental testing begins. This familiarization typically includes walking on the treadmill to determine work loads. Approximate work loads are estimated using prediction models. As volunteers exercise at these levels, expired air samples are collected using open circuit spirometry, and gases are analyzed to measure how hard (watts) the subjects are working. Work loads can then be adjusted to achieve the desired energy expenditure.

Familiarization may be conducted to instruct volunteers on placement of esophageal temperature probes. Individuals with a strong gag reflex may find it initially difficult to advance the probe past their epiglottis, but with proper instruction, most volunteers are able to successfully place this probe.

EXPERIMENTAL DESIGN

Experimental tests will be conducted under the same conditions for each CIE, as well as a control test using the currently fielded version. Each test will be conducted at the same time of day. A typical experimental test involves moderate intensity exercise (325-450 W) for 100 minutes; however, the duration of exposure and type of activity performed can be altered according to the requirements for the tested items. Clothing with high insulation levels and / or low permeability would require lighter work loads and lower heat stress to ensure the ability to perform prolonged work. Since dehydration limits exercise performance, fluid intake is recommended whenever possible (depending on the constraints of the CIE). The amount of fluid volunteers need to consume can be estimated from human simulation models, and from fluid losses observed during HA sessions. Nude body weight measurements should be made before and after experimental tests to ensure body weight is restored to within 1% of the baseline weight.

Environmental Conditions

Environmental conditions in the test chamber are controlled for dry bulb temperature, dew point or wet bulb temperature, black globe temperature and wind speed according to the conditions required by the specific evaluation, and to create the same thermal stress daily for each experimental trial. Temperature measurements are controlled within 0.5°C, and wind speed is controlled within 0.09 $m \cdot sec^{-1}$. Because the goal of some evaluations is to determine how long individuals can work under a specific thermal stress while wearing particular CIE, heat stress conditions are usually limited to no more than 49°C (120°F), 20% RH for hot, dry environment and 35°C (95°F), 75% RH for a hot, humid environment. For evaluations of CIE with high insulation and / or low permeability values, the hot, humid environment should be reduced to 35°C, 50% RH to increase the potential for evaporation through the clothing. This will allow for longer exercise performance and enhance the ability to analyze differences among physiological responses in the candidate CIE.

Solar radiation may be significant for Warfighters in desert environments or working on an open ship deck. Some CIE are designed to counteract the impact of the radiant heat; therefore, experimental design may require radiant load. An example of this is reflective inserts, which were evaluated with a radiant load to determine whether they were effective at reducing the amount of radiant energy absorbed by helmets and body armor (8). It should be noted that most solar panels do not provide full spectral distribution and, therefore, do not completely mimic the natural radiant environment. Any solar panel that is used for testing should be able to provide a radiant load from 500 - 1200 $W \cdot m^{-2}$ to simulate radiant loads from temperate through desert environments. The maximum radiant heat load of 1200 $W \cdot m^{-2}$ simulates a radiant temperature similar to working in the midday sun in the Middle East in summer.

Physiological Measurements

An important and sensitive measurement of thermal strain among CIE tested is core temperature. In the laboratory, use of either a flexible rectal thermometer or use of an esophageal probe ensures that temperature measurements are always made at the same anatomical location without bias from external environmental conditions (such as can occur with oral or tympanic temperature measurements)(37). The esophageal probe is inserted to a depth that places it in close proximity to the left atrium and, therefore, closely tracks blood temperature. However, the esophageal probe is incompatible with respiratory masks and cannot be used during evaluation of chemical protective garments. Another disadvantage of esophageal temperature measurement is that values are impacted by swallowing (saliva or water are at lower temperatures than blood temperature). When using the esophageal probe, volunteers are instructed to spit saliva into a cup during testing, and fluid intake is timed so that temperature measurements are not affected. For many CIE studies, rectal probes may be more suitable, particularly when rapid changes in body temperature are not expected. Both rectal and esophageal temperature probes may cause some discomfort during placement, but should not be uncomfortable during exercise.

Another method of measuring core temperature is with an ingestible telemetric core temperature pill. This technology has been demonstrated to be accurate and reliable during periods of increasing and decreasing body temperature (30). The pill is typically given 4-8 hours before testing to ensure that it has moved out of the stomach before testing begins. Since it is not in a stable position in the body, some changes in temperature may reflect location (e.g., pill temperature is higher when the pill is near more metabolically active tissue, but lower as it transits away from that tissue), rather than actual changes in body temperature. Transit time varies, which can be a problem when a series of trials are scheduled. If the volunteer excretes the pill on the morning of a scheduled trial, another pill must be given before testing begins. These pills can also be used as a rectal suppository and in this placement would be stable for the duration of the environmental exposure; however, this would be an expensive alternative to a rectal probe. Core temperature is monitored continuously and recorded at least once every minute.

Skin temperature is another important measure of thermal strain, and is often measured during CIE tests at a minimum of three sights. Skin temperature may be of interest at a specific site, but more often a mean weighted skin temperature is calculated using any of a number of accepted weighting formulas (24, 26). During cold stress, where there may be a concern about local cold injury (typically on the face, hands or feet), skin temperature may be measured at a larger number of sites. Sensors that measure both heat flux and skin temperature are often used during cold exposure to obtain more information about heat loss. Skin temperatures are monitored continually and recorded at least every minute.

Heart rate is a sensitive measure of thermal strain and is traditionally measured using bipolar electrodes, but these rarely remain in place with the high sweat rates that occur during exercise in hot environments. A more reliable method is the use of an electrode band worn around the chest with signal transmitted to a wristband receiver. Heart rate is monitored continually and recorded at least once every five minutes.

Metabolic rate during exercise is often measured during the Preliminary Measurements phase, but is also collected at least once during each experimental trial to ensure consistency among tests or to detect any differences due to variations in the tested CIE. If CIE tests require wearing gas masks, metabolic rates cannot be collected during testing, and the metabolic value collected during familiarization is used as the approximate work load for all tests.

Both nude and dressed weights are measured and recorded before and after every environmental exposure. Food and fluid ingested and any elimination from the body are also recorded after obtaining the initial nude weight. These values, corrected for respiratory water loss and CO_2-O_2 exchange (27), are used to calculate total sweating rate, as well as evaporative cooling from the CIE. Sweating rate is expressed per unit time and per unit surface area ($mg \cdot cm^{-2} \cdot min^{-1}$). Evaporative cooling is expressed in watts or watts per surface area.

Subjective measurements are often collected to provide additional information on user acceptability that can be of use to CIE developers. At set intervals during the environmental exposure, subjects may be asked to rate their perception of effort (4), thermal sensation (13), or thermal comfort (3).

Rate of heat storage (S, $W \cdot m^{-2}$) is calculated as mean body weight during each experimental trial (kg) x the specific heat constant (0.965 $W \cdot h \cdot ºC^{-1} \cdot kg^{-1}$) / body surface area ($m^2$) x the change in body temperature (ºC) per unit exposure time (h). The weightings of skin and core in the calculation for mean body temperature vary depending upon the environment. For example, during heat stress, core temperature has a weighting of 0.9 and skin of 0.1, whereas in experimental trials with microclimate cooling or during cold exposure, skin temperature would be weighted more heavily at 0.2, with core weighted at 0.8.

FIELD STUDIES

Human testing in field situations can also be performed; however, there is no control over environmental conditions. One approach is to have different groups of subjects wear a particular CIE configuration. This requires a larger number of subjects than the repeated measures design used in the laboratory, where each subject serves as his /her own control and variability is minimized. Logistically it may not be possible to obtain sufficient prototypes to outfit independent groups.

Aside from lack of control over environmental conditions, control over volunteer activity can be difficult in a field environment. Road marching is one task that can be successfully used for CIE evaluations. If marching time is recorded over a measured distance, then metabolic rate can be estimated using prediction models, and core temperature and heart rate data can be related to this metabolic rate. Meteorological measurements must be made so that they can be used as a covariate in analyzing between-day data.

COST

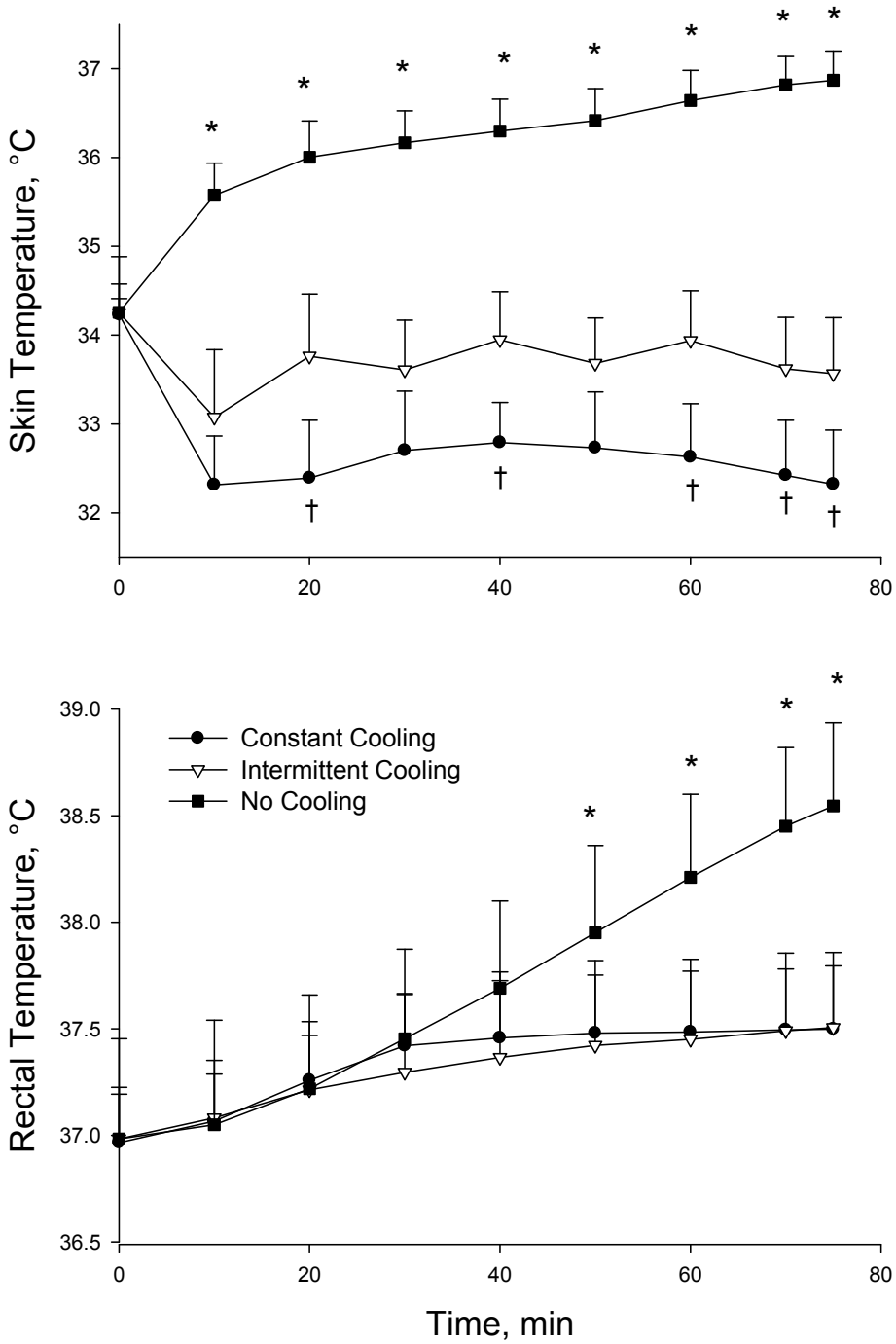
The cost of human testing increases with the number of configurations (CIE; environmental conditions; work / rest cycles; types of subjects) that are performed, particularly when there are time constraints. Field studies bear the expense of transporting all the monitoring equipment and research staff to the remote site required to carry out the study. Furthermore, unlike laboratory studies conducted in environmental chambers, equipment for field studies must be able to accommodate free-ranging individuals undergoing a wide variety of tasks. This typically requires untethered monitoring equipment.

DOCUMENTATION OF RESULTS

CIE evaluations often are required for decisions on further development, modifications, or acceptance. The primary results can be provided most quickly in a "letter report" that documents the key findings and comparisons. For example, final core temperature or endurance time (time to reach a target core temperature), and changes in core temperature, heart rate, sweating rate, and rate of heat storage may be presented for each CIE tested in each environment. This information will indicate whether heat strain is significantly different among the tested CIE. By comparing human physiological strain data on prototype CIE to existing CIE and using modeling to predict physiological strain under a wider range of conditions, potential hazards for thermal strain can be identified. This may result in recommendations for limitations of thermal stress, exposure duration, work rate, work duration, or work / rest cycles.

More detail, data analysis and interpretation are typically presented as a follow up in a technical report, such as USARIEM T07-02 (7). This may include analyses of core and skin temperature, heart rate, and sweating rate across time so that developers can see trend differences among CIE. An example of this is shown in Figure 2 for skin and rectal temperatures in volunteers wearing chemical protective clothing with no cooling, intermittent microclimate cooling and constant microclimate cooling during exercise at 30ºC, 30% RH. The graphs clearly show the effectiveness of microclimate cooling for limiting heat strain, as well as the greater efficiency of intermittent cooling, which cycled 2 min on, 2 min off. Perceptual data and volunteer feedback may also be included in final technical reports. A discussion section will interpret the results and may indicate a need or direction for future work.

Figure 2. Human physiological testing of cooling equipment shows increased skin (top panel) and core (lower panel) temperatures with No Cooling, reflecting heat strain. With Intermittent Cooling, skin temperature was ~1ºC higher than with Constant Cooling, but both cooling conditions were effective for Core Cooling. Intermittent cooling cycled 2 min on, 2 min off, thus was twice as efficient as Constant Cooling (6).



SUMMARY

This technical note describes the progression of procedures to support the HHA of thermal stress for candidate CIE. A comprehensive evaluation of thermal stress associated with CIE involves 1) biophysical measurements of the thermal insulation and moisture permeability of the textiles using a guarded hot plate, and of the CIE using thermal manikins; 2) biomedical modeling to predict physiological (body temperatures, sweating rate and heart rate) strain expected of persons wearing a particular CIE configuration under conditions of environmental (temperature, humidity, air motion, radiant lead) and metabolic (work, rest) stressors; and 3) human volunteer testing of CIE worn by persons exposed to a variety of controlled (laboratory or field) environmental / metabolic stressors. Human volunteers can also provide feedback on user acceptability. These data are used to determine how well new CIE performs relative to existing standards. The results of manikin, modeling, and human performance tests provide thermal stress information necessary for USACHPPM to complete an HHA.

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